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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,591	06/13/2000	Gary K. Michelson	101.0078-00000	5619

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/593,591

Applicant(s)

MICHELSON, GARY K.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-129 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-129 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, there is no enabling disclosure of how to make a combination of a bone ring also including bone composite material. Rather, only "cortical bone, plastics, and composite plastics" are described in the specification; see page 11, lines 11-12 of the original specification. There is no description of using a bone composite with the bone, and how any of these materials would be oriented with respect to each other. For this reason, one would not know how to make and/or use the claimed invention because there is no teaching of how to do so.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22, 25-35, 43-63, 66-77, 85-106, 109-119 and 127-129 are rejected under 35 U.S.C. 102(e) as anticipated by Boyle et al (US 6,277,149) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Boyle et al (US 6,277,149) alone.

Boyle discloses a bone ring obtained from a long bone (Figures 5, 10, 12, and column 2, lines 28-55). The leading edge straight section is met by the vertical edges formed along the axial axis of the cylindrical wall.

Alternatively, if one does not consider the Section 102 interpretation as untenable because the straight leading edge is not circumferentially oriented in Boyle, this interpretation would lead one to conclude that Boyle lacks the straight leading edge section as claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to flatten a side of the Boyle implant because Applicants have not disclosed that a flattened leading edge provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well. Furthermore, Boyle has some embodiments where there are flat circumferential surface. Therefore, it would have been an obvious matter of design choice to modify Boyle to obtain the invention as specified in the claims.

With regard to claims 26-29, 67-70, and 110-113, the location and composition of vertebral bodies is not defined. Therefore, the claim language is read on by the bone particles or bone growth material inserted into the opening (326) for example; see column 4, lines 10-13.

With regard to claim 29 specifically, since the screw is not positively claimed as part of the implant, its structure is not viewed as being positively required by the claim. For this reason, it is interpreted as an inferential recitation.

Claims 23, 24, 64, 65, and 107-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) in view of Zdeblick et al (US 5,669,909). Boyle et al meets or renders obvious the claim language but fails to disclose more than one bore through the upper and lower surfaces as claimed. Zdeblick et al, however, teaches that it was known to have more than one hole in similar implants; see the figures. Hence, it is the Examiner's position that it would have been obvious to have two or more holes in the Boyle et al implant for the same reasons that Zdeblick et al has the same and in order to promote greater ingrowth.

Claims 36-42, 72, 78-84, and 120-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) alone.

With regard to claims 36-42, 78-84, and 120-126, Boyle et al meets the claim language except for the types of growth promoting substances claimed. However, the Examiner posits that the type of growth promoting substance would have been prima facie obvious over Boyle et al alone because there is no criticality for such types shown or demonstrated. For example, in column 4, lines 10-13, Boyle discloses putting

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bone growth material into the opening (26). The specific type of bone implant material claimed would amount to a substitution of a functionally equivalent bone growth material for another one as disclosed by Boyle. For this reason, it would have been prima facie obvious to an ordinary artisan to substitute one bone growth material for another since the other one would function equally well.

With regard to claim 72, Boyle et al does not disclose the use of a bioresorbable plastic as claimed. However, the Examiner gave Official notice that bioresorbable plastics are known and used in the art. Applicant failed to traverse this assertion so the Examiner asserts that he acquiesced to the Examiner's assertion. Hence, it is the Examiner's position that it would have been obvious to do the same in the Boyle et al invention for the same reasons that the prior art uses the same.

Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) in view of Gross et al (US 5,306,308). Boyle et al does not disclose the use of a bioresorbable plastic as claimed. However, Gross et al (US 5,306,308) teaches that it was known to coat similar implants with the bioresorbable plastic polylactide in order to encourage bone ingrowth. Therefore, it would have been obvious to coat the Boyle et al implant with polylactide in order to promote bone ingrowth as taught by Gross et al.

Response to Arguments

Applicant's arguments filed March 14, 2003 have been fully considered but they are not persuasive.

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In particular, Applicant argues that Boyle fails to disclose a substantially straight front edge with a curved back edge. However, the Examiner has changed his interpretation of Boyle and has effectively rendered this argument moot.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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